

INFORMATION DISCLOSURE  
STATEMENT

Patent Application  
Docket No. SER-105

January 24, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Vincenzo De Leo, Antonio La Marca  
Docket No. : SER-105  
For : Use of Follicle Stimulating Hormone for Reduction of Spermatozoa  
Chromosomal Aberration in Males

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§1.97 AND 1.98

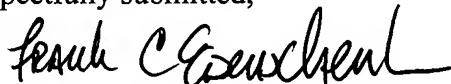
Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed. However, Applicants have not submitted a copy of the U.S. patent cited on attached Form PTO/SB/08 pursuant to 37 CFR 1.98(a)(2)(ii).

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

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Attachments: Form PTO/SB/08; copies of references cited therein

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

**Complete if Known**

Application Number

10/565763

Filing Date

January 24, 2006

First Named Inventor

Vincenzo De Leo

Art Unit

Examiner Name

Attorney Docket Number

SER-105

Sheet

1

of

2

**U.S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Document Number<br>Number - Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant<br>of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|--------------------|-----------------------|---|--------------------------------|--|---|
|                    | U1                    | US-5,017,557  | 05-21-1991                     | Fabbri <i>et al.</i>                               | All   |
|                    | U2                    | US-   |                                |  |   |
|                    | U3                    | US-   |                                |  |   |
|                    | U4                    | US-   |                                |  |   |
|                    | U5                    | US-   |                                |  |   |
|                    | U6                    | US-   |                                |  |   |
|                    | U7                    | US-   |                                |  |   |
|                    | U8                    | US-   |                                |  |   |
|                    | U9                    | US-   |                                |  |   |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Foreign Patent Document<br>Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup> |
|--------------------|-----------------------|--|--------------------------------|--|---|----------------|
|                    | F1                    |  |                                |  |   |                |
|                    | F2                    |  |                                |  |   |                |
|                    | F3                    |  |                                |  |   |                |
|                    | F4                    |  |                                |  |   |                |
|                    | F5                    |  |                                |  |   |                |
|                    | F6                    |  |                                |  |   |                |

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IAPO Rec'd 24 JAN 2006

PTO/SB/08B (08-03)

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|--|---|----|---|--------------------------|--|------------------|--|
| Substitute for form 1449B/PTO<br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |    |   | <b>Complete if Known</b> |  |                  |  |
|  |   |    |   | Application Number       |  | 10/565763        |  |
|  |   |    |   | Filing Date              |  | January 24, 2006 |  |
|  |   |    |   | First Named Inventor     |  | Vincenzo De Leo  |  |
|  |   |    |   | Group Art Unit           |  |                  |  |
|  |   |    |   | Examiner Name            |  |                  |  |
| Sheet  | 2 | of | 2 | Attorney Docket Number   |  | SER-105          |  |

| NON PATENT LITERATURE DOCUMENTS |                       |  |                |
|---------------------------------|-----------------------|--|----------------|
| Examiner Initials*              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.                                   | T <sup>2</sup> |
|                                 | R1                    | BEN-RAFAEL, Z. <i>et al.</i> "Follicle-stimulating hormone treatment for men with idiopathic oligoteratoasthenozoospermia before in vitro fertilization: the impact on sperm microstructure and fertilization potential" <i>Fertility and Sterility</i> , January 2000, pp. 24-30, Vol. 73, No. 1. |                |
|                                 | R2                    | BACCETTI, B. <i>et al.</i> "The effect of follicle stimulating hormone therapy on human sperm structure (Notulae seminologicae 11)" <i>Human Reproduction</i> , September 1997, pp. 1955-1967, Vol. 12, No. 9.   |                |
|                                 | R3                    | STREHLER, E. <i>et al.</i> "The Effect of Follicle-Stimulating Hormone Therapy on Sperm Quality: An Ultrastructural Mathematical Evaluation" <i>Journal of Andrology</i> , July/August 1997, pp. 439-447, Vol. 18, No. 4.  |                |
|                                 | R4                    |  |                |
|                                 | R5                    |  |                |
|                                 | R6                    |  |                |
|                                 | R7                    |  |                |
|                                 | R8                    |  |                |
|                                 | R9                    |  |                |
|                                 | R10                   |  |                |
|                                 | R11                   |  |                |
|                                 | R12                   |  |                |

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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